GENERAL PROCEDURAL POLICIES

CITIZEN PETITIONS POLICY AND PROCEDURES

Background:

An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. In addition, the request for a formal advisory opinion under 21 CFR 10.85 is processed as a citizen petition. The submission of citizen petitions is governed by §10.30. Petitions are submitted to the Division of Dockets Management (HFA-305) (DM) where they are reviewed for compliance with §10.30. If the petition is acceptable for filing, DM files, acknowledges, and assigns a docket number to the petition. If the petition is not adequate for filing, DM returns it to the petitioner.

1. Processing Citizen Petitions (excluding Suitability Petitions):

   DM forwards filed petitions to the appropriate Center or Office for preparation of a response. Under 21 CFR 10.30(e)(2), a written response to the petition is required within 180 days of filing. The response may consist of:

   a. Concurrence with the petition which may result in appropriate administrative action such as publication of a FEDERAL REGISTER document;

   b. Denial of the petition, which generally will include a discussion of the basis for denial;

   c. A tentative response, indicating why the agency is unable to reach a decision on the petition. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

   Final responses to citizen petitions are ordinarily the responsibility of Associate Commissioner for Regulatory Affairs. Appropriate FDA units prepare petition responses for his or her signature. When the citizen petition is closely related to a proposed or final rule, the final response will be prepared for the signature of the Associate Commissioner for Policy.

A petitioner whose petition has been denied may request administrative reconsideration under §10.33. A request for reconsideration is normally required to be submitted within 30 days of the denial.

The agency administrative record for the Citizen Petition is maintained by the Division of Dockets Management, showing: (1) The docket number (assigned by DM); (2) The date the petition was filed by the DM; (3) The name of the petitioner; (4) The subject matter involved; and (5) The disposition of the petition.

The Policy and Regulations Team, HFV-6, is the contact point within the Center for Veterinary Medicine (CVM) for receipt of the petition; coordination among offices, if necessary; consolidating the necessary reviews and actions; logging the movements of the petition and response package; circulating the response package for proper signatures and monitoring timeliness of response.

When received by HFV-6, the petition is logged into the CVM priorities list indicating Docket Number, the 180-day due date, and other identifying information, such as the name and mail code of the CVM unit(s) where it is assigned for consulting review and preparation of correspondence.

The preparation of the response to a Citizen Petition may be assigned to any unit within the CVM depending upon the expertise involved. The expertise and resources required for response are determined by the Associate Deputy Director of the Policy and Regulations Team, in conjunction with the appropriate Office Directors.

A final response to a citizen petition will be prepared for the signature of the Associate Commissioner for Regulatory Affairs unless the petition is closely related to a proposed or final rule. In the latter case, it will be prepared for the signature of the Associate Commissioner for Policy. The preparation of the response may be assigned to any unit within the Center depending upon the expertise involved. Under §5.31(e)(2), the Center Director may sign an interim response. The response should be accompanied by an action memorandum describing the nature of the petition and the rationale for the response with a recommendation that the letter be signed and issued. The docket number should be in the upper-right-hand corner of the first page. The distribution copy of the letter to be filed by Division of Dockets Management should not include concurrence and distribution information. At completion, HFV-6 determines that DM has received copies of all correspondence and memoranda relating to the docket (except internal working papers or memoranda (including action memorandum) that are protected from disclosure under the Freedom of Information Act).

Ordinarily a draft response will be prepared with the assistance of an attorney in the Office of Chief Counsel (OCC) assigned to review CVM matters. The response package should be circulated for signature of the appropriate Division Director, appropriate Office Director and Center Director. If the issue impacts on more than one division, it should be concurred in by each. Following final sign-off by the Center, responses for the signature of the Associate Commissioner for Regulatory Affairs are forwarded to the Division of Compliance Policy (HFC-230) who will log it into their tracking system. The package is then forwarded for OCC's final concurrence before it is forwarded to the Associate Commissioner for Regulatory Affairs (HFC-1) for signature, issuance of response, and distribution of copies, including those to DM. If the petition response involves a FEDERAL REGISTER publication, Regulations and Policy Management Staff (HF-26) will also be included in the review and it will be forwarded to the Associate Commissioner for Policy (HF-22) for signature.

Responses to petitions related to a proposed or final rule, and prepared for the signature of the Associate Commissioner for Policy, will be forwarded to the Regulations Policy and Management Staff (RPMS) (HF-26) following final sign-off by the Center. RPMS will obtain final OCC concurrence, signature, issue the response, and distribute copies.

2. Processing Suitability Petitions:

Suitability petitions for new animal drugs are defined in section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act, and are processed in CVM as a special type of citizen petition. If the sponsor wants to submit an abbreviated application for a new animal drug whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug, or whose use with other animal drugs in animal feed differs from that of an approved new animal drug, the sponsor must submit a suitability petition seeking permission to file such an application. 21 U.S.C. 360b(n)(3). Refer to P&P Manual 1243.3040 for specific information on how to process suitability petitions